

6/11/2020

Ms Deborah Anton  
Interim National Data Commissioner  
Department of Prime Minister and Cabinet  
One National Circuit  
Barton ACT 2600

## Consultation on the Data Availability and Transparency Bill 2020

Dear Ms Anton,

NPS MedicineWise is an independent, not-for-profit, evidence-based and consumer-centred organisation, working to improve the way health technologies, medicines and medical tests are prescribed and used.

NPS MedicineWise welcomes the opportunity to comment on the Office of the National Data Commissioner's (ONDC) 'Consultation on the Data Availability and Transparency Bill 2020'. The legislative package, which includes an exposure draft of the Bill (the Bill), the explanatory materials and a Discussion Paper on the draft Accreditation Framework, represents an important step around the future of data sharing in Australia and is of relevance to our MedicineInsight program.

### Public Sector Data definition

We note the draft Bill defines 'public sector data.' This definition establishes the scope of data that can be shared under the data sharing scheme. The term includes *data that is collected, created, or held by a Commonwealth body, or on its behalf.*

Clause 10(46) of the Explanatory Memorandum provides little further guidance on interpreting the definition of private and public sector data. We suggest the interpretation of the definition could be clarified in subsequent guidelines or the definition itself could be more precise. We further note that these concerns, on the ambiguity of what may be considered public sector data, have been raised to you previously by The College of General Practitioners<sup>1</sup>.

For background, our concern around this definition stems from the fact that NPS MedicineWise is the custodian of a large dataset which is collected pursuant to the MedicineInsight Program. MedicineInsight was established by NPS MedicineWise in 2011, with core funding from the Australian Government Department of Health, to support quality improvement in Australian primary care and the post-market surveillance of medicines. MedicineInsight is a large-scale primary care database of longitudinal de-identified electronic health records (EHRs) in Australia. The MedicineInsight program collates routinely collected EHR data from clinical information systems (CISs) from consenting general practices which have agreed to provide data on an ongoing basis.

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<sup>1</sup> See [RACGP submission](#)

## Defined purposes test and ethical requirements

The Bill and explanatory materials indicate that '*the sharing must be reasonably necessary to inform government policy, programs or service delivery, or be in support of research and development*'. Data custodians will be required to apply this test as a gateway into the data sharing system.

NPS MedicineWise is generally supportive of the scope of this purpose test described at section 15 of the Bill. In our view these purposes are broadly reflective of community expectations for data sharing. The MedicineInsight program operates on a similar basis, with Human Research Ethics Committee (HREC) approval to share data for similar purposes, and data governance principles aligned to the Five Safes Framework.

The sharing of MedicineInsight data is always demonstrably tested against the program's approved ethical purposes. However in our experience, whether specified by ethical approval (or authority under legislation) a compliance based, deontological approach to data sharing purposes cannot negate the need for robust ethical assessment and dialogue<sup>2</sup>. This is particularly the case for omnibus legislation like the Data Availability and Transparency Bill 2020<sup>3</sup>.

We recommend that the purpose test is enumerated by examples in guidelines. In conjunction with the proposed data access register, examples should include the rationale of how the data custodian meets the purpose test, including substantiation by data custodians of how ethical issues have been considered.

NPS MedicineWise understand that the purpose test is not meant to impose a new formal ethics requirement to replace the provisions in the Privacy Act 1988 (Cth) or NRHMC ethical oversight. However, the operation of the legislation will need to balance necessary ethical oversight, while managing the risk of further contributing to the duplication in governance and ethical responsibilities between HRECs and data custodians<sup>4</sup>.

NPS MedicineWise recommends that existing ethical arrangements should be fully considered, and that data custodians should establish that any data release proposed under the legislation demonstrates equal or more appropriate privacy safeguards and governance efficiencies.

## Commercial purposes

The use of data for commercial purposes raises additional privacy impacts that require a cautious and thorough examination to ensure that community trust in the system is maintained. This is particularly the case with health data. If Australians lose confidence in the privacy protections applied to sensitive health information, there is a possibility some patients will not seek medical treatment<sup>5</sup>.

The ONDC has stated that data sharing for commercial purposes can also be of great benefit to the public when it is done safely and effectively, and by example describe; *where a research*

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<sup>2</sup> See [RACGP ethical considerations](#)

<sup>3</sup> As [stated by the ONDC](#) 'data sharing reforms will require much more than legislation'

<sup>4</sup> See for example a [suggested division](#) of HREC and data custodian roles to avoid duplication

<sup>5</sup> See [Australian Medical Association submission](#)

*project to improve pharmaceutical treatments for heart disease could deliver both profits for the researcher as well as a public health benefit<sup>6</sup>.*

NPS MedicineWise agree there is risk and benefit in the use of data for commercial purposes which must be managed with care. We are uniquely placed to comment on these issues having experience in data release for multiparty research, involving HREC approval and commercial partnerships<sup>7</sup>.

We support the current Bill which does not seek to define or prohibit ‘commercial activities’ separate to ‘permitted purpose’. Importantly the use of data for commercial purposes is not prohibited by the Privacy Act 1988 (Cth) and does not form a criterion for ethical decision making under national health and medical research guidelines<sup>8</sup>.

In the absence of a national regulatory framework, the MedicineInsight program has been guided by organisational, industry and ethical guidelines which ensure privacy impacts are appropriately minimised. We recommend the following mechanisms and controls which may be incorporated into ONDC guidelines on data release that may involve commercial partnerships:

1. Organisational research charters and oversight committees<sup>9</sup>.
2. Adherence against relevant Industry Codes of Conduct<sup>10</sup>.
3. Pre-existing ethical guidelines produced by statutory authorities<sup>11</sup>.
4. HREC approval.

We commend the ONDC for the transparency of Clause 110 of the Explanatory Memorandum, as recommended by the most recent Privacy Impact Assessment; it is important this clearly outlines the fact that approved purposes under the legislation may include commercial activities.

## **Data Linkage**

Clause 46 of the Explanatory Memorandum states that data created or enhanced by an Accredited Data Service Provider (ADSP) on behalf of a data custodian (refer clause 11(4)(b)) falls within this definition of subclause 2 and therefore is considered ‘public sector data’. Further Clause 47 of the Explanatory Memorandum states ‘*This includes where the ADSP integrates public and non-public sector data on behalf of a data custodian*’.

In this circumstance the integrated dataset is transformed to ‘public sector data’ as it is data created on behalf of the Commonwealth (the data custodian). NPS MedicineWise has concerns that this may lead to erosion of privacy safeguards, where private and public data is linked (integrated).

Effectively, the legislative framework provides that private sector data, once linked to, for example, to the PBS or National Death Index becomes public sector data. NPS MedicineWise therefore

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<sup>6</sup> See Clause 110 of the Explanatory Memorandum

<sup>7</sup> See for example MedicineInsight [partnership funded research](#)

<sup>8</sup> See the [National Statement on Ethical Conduct in Human Research](#)

<sup>9</sup> These may include Research Advisory Groups, and [Data Governance Committees](#).

<sup>10</sup> Commercial partnership applications involving MedicineInsight data release have demonstrated amongst other matters adherence to the [Medicines Australia's Code of Conduct 19](#), and the [Uniform Requirements for Manuscripts \(URMs\)](#) developed by the International Committee of Medical Journal Editors.

<sup>11</sup> MedicineInsight is guided by the [NHRMC Conflict of Interest Guidelines](#), and the [NHRMC Ethical Considerations](#) in Quality Assurance and Evaluation Activities in these matters.

recommends that privacy safeguards for data linkage ensure separation of content data from any resulting 'enhanced ADSP' dataset.

Further, and as noted by the Privacy Commissioner<sup>12</sup>, data within scope of the Bill provides the potential to allow government agencies to override existing use and disclosure provisions of the Privacy Act 1988 (Cth) that apply by relying on the 'required or authorised by law' exception to Australian Privacy Principle (APP) 6 for Australian Government agencies. This too can be viewed as an erosion of existing privacy safeguards.

**Accreditation framework: Are there elements of data capability that should be given more or less weight in the accreditation process, i.e. making elements mandatory or optional?**

In response to this specific question posed by the accreditation framework consultation, NPS MedicineWise recommend that a high-level weighting should apply to the assessment of accreditation. For example, the MedicineInsight program requires a risk assessment of each application, which includes a detailed Secure Research Environment Assessment.

Our assessment of each external secure environment is undertaken using a maturity model approach, which broadly assesses on modalities of *none, partly, mostly and full* compliance to our accreditation requirements<sup>13</sup>. The domains of Secure Environment Assessment are not formally weighted. However, all assessment is undertaken by a Certified Information Security Professional.

**Accreditation framework: What elements would be most useful to Data Custodians to support their decision-making process when considering sharing and access to data? Are there further ways we can streamline the accreditation process?**

A threshold issue for the accreditation scheme, and one which may streamline the accreditation process further, is to ensure ongoing consistency, mapping, and recognition across all other relevant accreditation requirements<sup>14</sup>. Given the risks of ever-increasing regulatory burdens preventing data sharing<sup>15</sup>, the consistency and recognition arrangements of the accreditation scheme are as important as the criteria. The accreditation scheme should ideally work to provide a national mapping of existing and emerging regulations and accreditation. This is also in line with the principles of the Commonwealth's draft National Health Information Strategy<sup>16</sup>.

NPS MedicineWise thanks the ONDC for the opportunity to contribute to this important legislation.

Yours Sincerely

Andrew McAlister

Data Governance Specialist  
NPS MedicineWise

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<sup>12</sup> See [QAIC submission](#)

<sup>13</sup> This approach aligns with the Essential Eight Maturity Model approach endorsed by Australian Signals Directorate's Australian Cyber Security Centre (ACSC)

<sup>14</sup> These may include the existing Integrating Authority Accreditation,

<sup>15</sup> See views of the [Australian Law Reform Commission](#) on these matters

<sup>16</sup> See principles of the NHISI that "There is clear and nationally unified governance with clarity about decision-makers, decision-making and approaches to investment".